IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia; JOHN BERNABEI, in his official capacity as a member of the West Virginia Board of Pharmacy; JAMES RUCKER, in his official capacity as a member of the West Virginia Board of Pharmacy; JENNA MISITI, in her official capacity as a member of the West Virginia Board of Pharmacy; SAM KAPOURALES, in his official capacity as a member of the West Virginia Board of Pharmacy; DAVID BOWYER, in his official capacity as a member of the West Virginia Board of Pharmacy; DENNIS LEWIS, in his official capacity as a member of the West Virginia Board of Pharmacy; ROBERT DUNCAN, in his official capacity as a member of the West Virginia Board of Pharmacy; ALLAN MCVEY, in his official capacity as Insurance Commissioner,

***Defendants*.**

Civil Action No. 2:24-cv-00271

Judge: _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. West Virginia Senate Bill 325, recently enacted into law, is preempted by federal law, and violates the First Amendment to the United States Constitution, as well as the United States Constitution's bar on extraterritorial regulation. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brings this Complaint and states as follows:

PRELIMINARY STATEMENT

2. The federal 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), requires that drug manufacturers whose products are eligible for reimbursement under Medicare Part B and the Federal Financial Participation under the Medicaid program must offer steep price reductions on covered outpatient drugs to 15 specified types of eligible healthcare providers ("covered entities"). 42 U.S.C. § 256b(a)(1). Congress authorized the Secretary of Health and Human Services ("HHS") to enforce and resolve disputes under 340B through a range of carefully balanced federal administrative mechanisms designed to incentivize drug manufacturer participation in each of these programs. *Id.* § 256b(d). The obligations of drug manufacturers to offer 340B pricing are provided by statute and by federal contract—a Pharmaceutical Pricing Agreement ("PPA") between each manufacturer and HHS.

3. At the heart of this litigation is an effort by PhRMA and its member drug manufacturers to protect the integrity of 340B. Congress created 340B to help underserved patient populations who receive treatment at covered entities. But over recent years, the federal program has morphed into a money-making enterprise for national pharmacy chains and others who seek to enrich themselves at the expense of these underserved patients. For-profit pharmacy interests, acting in concert with covered entities and others, improperly leverage 340B pricing for their own financial advantage, often without providing any benefits to the vulnerable patient populations 340B was intended to help. Most recently, state legislatures in West Virginia and elsewhere have intervened on the side of those who have improperly benefited from 340B. These intrusions are

not aimed at ensuring patient access to drugs—instead they directly and intentionally seek to provide 340B-pricing to those entities not entitled to it under federal law.

4. The United States Supreme Court has previously invalidated efforts to distort and undermine the quintessentially *federal* nature of 340B. In *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), the Court rejected an effort by a group of county medical facilities (covered entities) to enforce 340B drug pricing requirements outside the federal administrative mechanisms provided in the 340B statute. The Supreme Court explained that 340B must be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120 (stressing the "interdependent nature of [340B and Medicaid]" and explaining that "an adjudication of rights under one program must proceed with an eye towards any implications for the other").

5. This case concerns West Virginia Senate Bill 325 ("SB 325"), which requires drug manufacturers to provide 340B-priced drugs to an unlimited number of pharmacies, including for-profit pharmacies, (so-called "contract pharmacies") who have independent agreements with covered entities. SB 325 provides for extensive state law penalties, including a fine of $50,000 per violation—defined as a manufacturer's failure to comply with SB 325 for each package of drugs—if drug manufacturers participating in the federal program do not also comply with SB 325's new and additional state law requirements. W. Va. Code § 60A-8-6a(c)(1)(A). Thus, in direct contravention of the Supreme Court's reasoning in *Astra*, SB 325 creates an alternative state law mechanism to compel manufacturers to give federal 340B price reductions in a manner directly at odds with federal law. SB 325 also bars manufacturers from requesting information related to 340B-priced drugs—information that manufacturers rely on to conduct audits as a pre-requisite to access the federal dispute resolution mechanism.

6. SB 325, unambiguous about its goals, specifically identifies its target—federal "340B drug[s]," *i.e.*, "covered outpatient drug[s] within the meaning of 42 U.S.C. § 256b." W. Va. Code § 60A-8-6a(a)(1)(A). In its three pages, SB 325 refers to the federal 340B statute a dozen times.

7. SB 325 is a transparent attempt to regulate drug pricing by imposing federal 340B price reductions where they would not apply under federal law. Understanding that it cannot legally mandate 340B pricing in this way, West Virginia and others have tried to rationalize SB 325 as simply a drug "delivery" regulation. But there is *no dispute* that West Virginia pharmacies can already order and receive delivery of the drugs at issue at market prices. The only question is whether and when the reduced federal 340B price applies.

8. Under the Supremacy Clause of the United States Constitution, West Virginia has no authority to define who has access to 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That is an exclusively federal responsibility. Nor can West Virginia legally punish drug manufacturers who do not provide 340B pricing to the entities West Virginia prefers.

9. Specifically, SB 325 seeks to expand 340B drug pricing through a mechanism in Subsection (b) of the regulation, W. Va. Code § 60A-8-6a(b), relating to what are commonly known as "contract pharmacies." Over the past decade, concerns about abuse, and illegal "duplicate discounts" in the 340B program have skyrocketed as covered entities have teamed up with so-called "contract pharmacies"—mostly for-profit pharmacies—nationwide to find ways to maximize the volume of 340B drug price reductions. Under the now prevailing "replenishment model," contract pharmacies first order drugs at market prices, and then, following sale of those drugs, seek to replenish their inventories with 340B-priced drugs by retroactively identifying, via black-box algorithms, drugs that are purportedly eligible for 340B pricing. As a result, the volume

of drugs purchased at reduced 340B pricing has exploded, more than tripling over the past decade, without any corresponding growth in the patient population. *See infra* at ¶¶ 37, 64. In 2022, 340B purchases reached *$53.7 billion*, a $9.8 billion increase from 2021 and a nearly $50 billion increase from 2009.[1] And because the contract pharmacies claim the 340B pricing retroactively, many of these 340B price reductions are not passed on to the indigent or underserved patients actually receiving the drugs.

10. The United States Government Accountability Office and the HHS Office of the Inspector General have warned about the risk of abuse by covered entities and use of the replenishment model, and a number of drug manufacturers, including many PhRMA members, have identified specific concerns and independently adopted policies to attempt to minimize that risk of abuse. *See infra* at ¶¶ 65, 79. Although the exact contours of the policies differ, they are all intended to curb abuse, and generally provide a limit on the number of outside pharmacies with which a covered entity may contract to receive 340B-priced drugs and require the contract pharmacy to submit data supporting their claims for the 340B discounts.

11. Following the Supreme Court's decision in *Astra*, covered entities appeared to understand that any disputes regarding the entities eligible for 340B-priced drugs, including those centered on contract pharmacy use, presented issues of federal law. Indeed, multiple covered entities filed petitions under § 256b(d)(3) with the federal agency seeking to resolve those contract pharmacy issues. One group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling

[1] Adam J. Fein, *The 340B Program Reached $54 Billion in 2022 – Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://tinyurl.com/2nrux6et; Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S. Cal. (Oct. 14, 2021), https://bit.ly/3FFSemV.

price through Petitioner's contract pharmacy arrangements." *See infra* at ¶ 87. Those entities asked HHS "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." *Id*. Another group of covered entities maintained in a 2023 filing that HHS had jurisdiction over its contract pharmacy dispute under the 340B statute because it "has authority to enforce the 340B statute." *See infra* at ¶ 87.

12. Eventually, multiple federal courts addressed drug manufacturers' 340B obligations as to 340B-priced drugs shipped to contract pharmacies. To date, four federal courts have rejected the argument that drug manufacturers have an obligation to deliver 340B-priced drugs to an *unlimited number* of contract pharmacies located anywhere in the United States, regardless of the circumstances. *See infra* at ¶¶ 14, 45-46, 82-86. Instead, courts have recognized that the relevant question is whether manufacturers have complied with the federal statutory requirement that they "shall offer" 340B-priced drugs to covered entities. *Id.* at ¶¶ 15, 45, 82-83; *Novartis Pharms. Corp. v. Johnson*, Nos. 21-5299, 21-5304, 2024 WL 2279829 (D.C. Cir. May 21, 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 703-06 (3d Cir. 2023) ("*Sanofi*"); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *5-7 (D.D.C. Nov. 5, 2021), *aff'd sub nom. Novartis*, 2024 WL 2279829 (D.C. Cir. May 21, 2024). More specifically: Must a good faith "offer" by a drug manufacturer under 42 U.S.C. § 256b(a)(1) also include an undertaking to deliver 340B-priced drugs to every pharmacy anywhere, including to pharmacies hundreds or thousands of miles from the covered entities where patients are treated? The answer is no. *Sanofi*, 58 F.4th at 703-06; *Novartis*, 2024 WL 2279829 at *8; *Novartis*, 2021 WL 5161783, at *5-7.

13. In response to those adverse federal court decisions, covered entities' representatives have turned to the states, arguing that states can mandate that drug manufacturers provide 340B-priced drugs to any contract pharmacy anywhere, even where federal law does not require it. West Virginia is one of nine states so far to pass such a law.

14. Laws like SB 325, however, rely on a misreading of the *Sanofi* case, which did not rule that the federal 340B statute left a gap that states are empowered to fill with their own preferred manufacturer obligations. As that court explained clearly, the question posed was not whether an obligation exists under federal law to deliver 340B-priced drugs to one, or a limited number, of contract pharmacies. *Sanofi*, 58 F.4th at 703-04. The question instead was whether the federal law *unambiguously* mandated delivery to an *unlimited number* of pharmacies, no matter where those pharmacies were. *Id.* at 703. The *Sanofi* court concluded that manufacturers' obligations under federal law were nowhere near as broad as the covered entities wished they were. *Id.* at 704. That decides the matter here as well.

15. The D.C. Circuit's recent opinion in *Novartis* confirms this principle. Construing 340B's requirement to "offer" 340B-priced drugs to covered entities, the court explained that Congress's choice "preserve[d]—rather than abrogate[d]—the ability of sellers to impose at least some delivery conditions." *Novartis*, 2024 WL 2279829, at *5. As in *Sanofi*, the court made clear that Congress imposed some constraints on how manufacturers may operate vis-à-vis "offers" of 340B-priced drugs. *Id.* at *7-8. Each manufacturer offer must be "bona fide," which the court stated meant that certain "onerous conditions might violate the statute." *Id.* at *8. But that determination is for the federal government, reviewed by federal courts, to make. *Id.* ("Likewise, we do not foreclose the possibility that these conditions may violate section 340B as applied in particular circumstances—if, for example, [the Health Resources and Services Administration

("HRSA")] could show that a specific covered entity for some reason could not supply the claims information demanded by United Therapeutics."). Accordingly, any purported Congressional silence here is not an invitation for states to wade into the space. In *Novartis*, the court concluded that a manufacturer's one contract pharmacy policy complied with its obligations under the federal 340B statute to make a *bona fide* offer. In other words, the manufacturer's obligations to provide the federal 340B price only extends to shipments directly to covered entities *or* to one contract pharmacy for each covered entity.

16. To administer and enforce SB 325, West Virginia would necessarily intrude into and interfere with the federal program by making multiple decisions uniquely committed to the federal agency and the federal courts under federal law. *For example*, West Virginia would need to resolve, in any given case based on the individualized facts before it, questions including whether a covered entity holds title to 340B-priced drugs at all times, whether the individuals who received such drugs were covered entity "patients" (to comply with the federal diversion prohibition) and whether a covered entity and a contract pharmacy have the necessary "principal-agent" relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B). Additionally, a covered entity that violates the provisions of the 340B statute is, under the explicit provisions of 42 U.S.C. § 256b(a)(4)-(5), ineligible to receive any 340B-priced drugs. So West Virginia must make that determination, too. These are all questions of federal law, committed exclusively to the federal agency and federal courts only. West Virginia cannot enforce SB 325 without rendering decisions on these core federal issues. If West Virginia and other states can do this, the uniform federal program will cease to be federal or uniform. Instead, states applying their own laws would make all key decisions. This directly contradicts the Supreme Court's reasoning in *Astra*.

17. SB 325's penalties also conflict with the carefully balanced provisions in the federal statute. SB 325 imposes additional penalties, assessed under different criteria, not provided for in federal law, on top of pre-existing carefully calibrated federal penalties. The threat of draconian penalties imposed by states, including West Virginia's staggering civil penalty of $50,000 per violation, will transform 340B into something Congress never intended. Drug manufacturers may decide to opt out of key federal programs as a result, defeating the carefully balanced purposes of 340B entirely. *See Astra*, 563 U.S. at 120 (noting the balancing required and the danger of "HHS [being] unable to hold the control rein"); *see also Novartis*, 2024 WL 2279829, at *6 (noting federal government's argument that 340B's "enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive").

18. In addition to being preempted under the federal Constitution's Supremacy Clause, SB 325's bar on manufacturers' speech violates the First Amendment. SB 325 bars manufacturers "directly or indirectly" from requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to" a covered entity or contract pharmacy "unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(2). This provision, which is both content- and speaker- based, is an unconstitutional restriction on manufacturers' speech. And, among other things, this unconstitutional restriction limits manufacturers' ability to perform the audits that 340B expressly permits. As the U.S. District Court for the District of Columbia has noted, a manufacturer policy requiring data submissions to verify that prescriptions came from covered entities "enable[s] it to better utilize the anti-fraud audit and [federal enforcement] procedures that Congress established for manufacturers in Section 340B." *Novartis*, 2021 WL 5161783, at *8.

19. Finally, SB 325 violates the Constitution's prohibition on state extraterritorial regulation. SB 325 is a textbook violation: It directly regulates wholly out-of-state transactions.

20. PhRMA brings this action to declare unlawful this improper state intrusion into the federal 340B scheme and to enjoin preliminarily and permanently Defendants from enforcing SB 325 against PhRMA's members and as to the sale of their drugs.

PARTIES

21. PhRMA, a trade association representing the nation's leading innovative biopharmaceutical research companies, advocates for policies that encourage the discovery and development of important new pharmaceutical products. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply their drugs at a steeply reduced price to West Virginia pharmacies under SB 325 or otherwise face significant monetary penalties. Neither the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

22. Defendant Patrick Morrisey is the Attorney General of West Virginia, the chief law enforcement officer of the state. The Attorney General is given enforcement authority over the challenged legislation. W. Va. Code § 60A-8-6a.

23. Defendants, John Bernabei, James Rucker, Jenna Misiti, Sam Kapourales, David Bowyer, Dennis Lewis, and Robert Duncan, in their official capacities as members of the West Virginia Board of Pharmacy, are given authority to implement and enforce the challenged legislation. *Id.* § 60A-8-6a(c)(3).

24. Defendant, Allan McVey, in his official capacity as Insurance Commissioner, has enforcement authority over violations of West Virginia's Unfair Trade Practices Act. *Id.* § 33-11-6.

JURISDICTION AND VENUE

25. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

26. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

27. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

28. Venue is proper in this district because this action challenges a West Virginia law applicable to the sale of PhRMA's members' drugs in this district, and thus SB 325 purports to directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within this district. 28 U.S.C. § 1391(b)(2).

29. Substantial amounts of PhRMA's members' drugs are sold under the 340B program to covered entities in this district. For example, HHS's website reflects that there are over 170 covered entities in the Southern District of West Virginia. *See* HRSA, Covered Entity Search Criteria, https://340bopais.hrsa.gov/coveredentitysearch. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, SB 325 is likely to be enforced against PhRMA members in this district.

30. Venue is also proper in this district because Defendant Attorney General maintains an office in Charleston, West Virginia, which is located in this district. 28 U.S.C. § 1391(b)(1).

BACKGROUND

A. The History of 340B

31. Congress established 340B in 1992 to restore drug discounts that had been provided voluntarily by manufacturers to a select group of safety-net providers before Congress passed the Medicaid Drug Rebate Program ("MDRP") in 1990. Indeed, Congress carefully restricted the list of eligible 340B covered entities to certain enumerated types of entities that "provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992) ("House Report").

32. Prior to the enactment of 340B, drug manufacturers had offered discounts on certain outpatient drugs on a voluntary basis to direct healthcare providers like covered entities, but not to pharmacies. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29-30 (2019) ("Prior to the MDRP, drug manufacturers regularly offered discounts to . . . hospitals and other safety net providers"). However, when Congress passed the MDRP in 1990, that law took the manufacturers' previous *voluntary* "large discounts" to safety net providers like covered entities and factored it into the calculation of *required* "best price" for purposes of determining Medicaid rebates. *Id.* at 29-30. The "unintended consequence" of this pricing "snafu" was that drug manufacturers were "disincentivized" from continuing to provide the voluntary discounts they had provided to safety net providers prior to the MDRP's passage. *See id.*; *see also* H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992).

33. Congress created 340B to address the limited problem created by the MDRP's enactment, specifically to restore the discounts that were previously offered voluntarily by manufacturers. *See* Pub. L. No. 102-585, 106 Stat. 4943, 4962; *see also* House Report at 12. When Congress passed 340B, the legislative history indicates that it intended to restore "discounts to

these clinics, programs, and hospitals," i.e., "direct clinical care" entities, which had previously received voluntary discounts. House Report at 12.

34. When it passed the 340B law in 1992, Congress estimated that the Program would only include approximately 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS drug purchasing assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers that qualified to participate. *Id.* at 13.

B. The Operation and Growth of 340B

35. 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as "covered entities," that provide healthcare to certain underserved populations. *Pharm. Rsch. & Mfs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (quoting *Astra*, 563 U.S. at 113).

36. In 2022, 340B-priced purchases reached *$53.7 billion, a $9.8 billion increase from 2021 and a nearly $50 billion increase from 2009*. Adam J. Fein, *The 340B Program Reached $54 Billion in 2022 – Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://tinyurl.com/2nrux6et ("Fein 2023"). There has been no similar increase in the relevant underserved patient populations that could explain this explosive growth.

37. That same year, the list price value (*i.e.*, based on wholesale acquisition cost) of 340B purchases was $106 billion. *Id.*; *see also* Rory Martin, PhD, *The 340B Drug Discount Program Exceeds $100B in 2022*, IQVIA (Apr. 14, 2023), https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-exceeds-uds100b-in-2022. That is equal to "more than 16% of pharmaceutical manufacturers' total gross sales of brand-name drugs at list prices." Fein 2023. If this recent growth trend continues unabated, 340B is estimated to become the "largest federal drug program

by 2026 exceeding gross drug purchases through Medicare Part D, Medicare Part B and Medicaid." Berkeley Rsch. Grp., 340B Program at a Glance (2021), https://tinyurl.com/ms2afa2y.

38. 340B is governed by a federal statutory framework, implemented by the HRSA, a federal agency within HHS.

39. Under 340B, participating manufacturers "*shall offer*" to each "covered entity" (as delineated by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute), *if* such drugs are offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That requirement does not involve an obligation to provide 340B-priced drugs to an unlimited number of contract pharmacies. *See infra* at ¶¶ 45-46, 82-86.

40. Federal law defines "covered entity" for purposes of 340B to mean an entity that "is one of" 15 types of specifically enumerated categories of healthcare providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-priced drugs and does not seek or cause a duplicate Medicaid discount (*see infra* at ¶ 59). 42 U.S.C. § 256b(a)(5).

41. Federally Qualified Health Centers, children's hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as "covered entities" eligible to enroll and participate in 340B. 42 U.S.C. § 256b(a)(4); *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Retail pharmacies are not among the listed covered entities. Indeed, *no* pharmacies and *no* for-profit entities are included as "covered entities." 42 U.S.C. § 256b(a)(4).

42. Federal law defines the "ceiling price" for purposes of 340B to mean "the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1). The ceiling price is the highest price a manufacturer may charge to 340B covered entities for a covered outpatient drug on 340B-eligible purchases. That ceiling price is deeply reduced compared to the drug's market price.

43. Manufacturers must "offer" their covered outpatient drugs at or below the applicable "ceiling price" to "covered entities," and only "covered entities" may receive this pricing under the express terms of federal law. *See id.*

44. Identifying the specific obligations imposed by 340B's "shall offer" provision on drug manufacturers requires the interpretation of 42 U.S.C. § 256b(a)(1) under federal law. According to courts that have reviewed this question to date, a drug manufacturer's appropriate good faith offer means that the manufacturer must provide some meaningful path for covered entities to obtain these medications at the 340B price. *See* 42 U.S.C. § 256b(a)(1); *Novartis*, 2024 WL 2279829, at *5; *Sanofi*, 58 F.4th at 703. But the statute does not mandate a commitment to provide 340B-priced drugs to an unlimited number of contract pharmacies of a covered entity's choosing. *Novartis*, 2024 WL 2279829, at *6 ("The requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree."); *see also Sanofi*, 58 F.4th at 703.

45. Indeed, "Congress's use of the singular 'covered entity' in the [statute] suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Sanofi*, 58 F.4th at 704; *see also Novartis*, 2024 WL 2279829, at *1 (stating that "Congress *has limited* the section 340B program in three important ways," including by defining "'covered entity' to mean only healthcare providers that fit within narrow

categories" (emphasis added)). And "[n]o other language in Section 340B requires delivery to an unlimited number of contract pharmacies." *Sanofi*, 58 F. 4th at 704.

46. To the contrary, the 340B statute forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B).

47. Congress has not expressly commanded pharmaceutical manufacturers to participate in 340B. *See Astra*, 563 U.S. at 117-18. Instead, participation in 340B is generally understood as a condition for manufacturers' covered outpatient drugs to be eligible for reimbursement under either Medicare Part B or the federal share of Medicaid (in general, programs that provide elderly and financially needy patient populations access to health coverage). 42 U.S.C. § 1396r-8(a)(1), (5); *see also Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579-80 (2012).

48. Manufacturers "opt into" 340B by signing a form federal contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That form contract is known as the PPA. *Id.* at 117. PPAs do not meaningfully vary between manufacturers, but "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118.

49. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from the 340B program. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). The manufacturer, in turn, may be forced to withdraw from participating in Medicare Part B and Medicaid, and their drugs will no longer be eligible to receive reimbursements under those programs, which would have a profound

impact on many vulnerable patient populations and our healthcare system. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

50. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B's oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation of the 340B program. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120.

51. Congress has also carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audits, a process known as administrative dispute resolution ("ADR"), and an enforcement scheme directed by HHS. For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

52. The imposition of penalties for violating 340B is directly committed to HHS: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs.

53. Specifically, HRSA may seek to have HHS impose civil monetary penalties of nearly $6,813 "for each instance of overcharging" a covered entity. Annual Civil Monetary

Penalties Inflation Adjustment, 88 Fed. Reg. 69,531, 69,535 (Oct. 06, 2023) (final rule); *see also* 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price." Congress has specified that these civil monetary penalties can attach to manufacturers only where they "knowingly and intentionally" overcharge. 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

54. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of HHS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR).

55. These regulations must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by manufacturers that violations of [statutory prohibitions on unlawful transfers of 340B drugs and duplicate discounts] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)); *see* 42 C.F.R. § 10.20 (setting out requirements for ADR review panels). According to those regulations, claims adjudicated through ADR can include, among others, "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug[.]" 42 C.F.R. § 10.21(c)(1); *see also* 89 Fed. Reg. 28,643, 28,657 (Apr. 19, 2024) (amended rule scheduled to go into effect on June 18, 2024). As explained below, *infra* at ¶ 87, covered entities have previously taken the position that the ADR process applies to claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B "ceiling price," including through manufacturer "contract pharmacy" policies.

56. HRSA regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii).

57. To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

58. Covered entities must also comply with additional requirements under 340B. As explained above, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (prohibiting unlawful transfers). Covered entities are also prohibited from seeking or causing unlawful "duplicate discounts or rebates" from manufacturers. *Id.* § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug. A covered entity that engages in unlawful transfers or duplicate discounting, which would violate § 256b(a)(5), no longer qualifies as a covered entity under the federal statute. *Id.* § 256b(a)(4) (specifying that to qualify as a covered entity, the entity must "meet[] the requirements described in paragraph (5)"). Whether a healthcare entity qualifies as a "covered entity" is a decision entrusted to the federal government.

C. Contract Pharmacy Abuses

59. As noted above, 340B requires that a manufacturer offer 340B pricing only to a "covered entity." 42 U.S.C. § 256b(a)(1).

60. Retail pharmacies are not "covered entit[ies]," so they are ineligible to receive 340B pricing.

61. But certain private, for-profit entities—including the largest national chain pharmacies—have, in increasing numbers, sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is typically accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and other entities like a third-party administrator.

62. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities. Inevitably, and at great financial benefit to themselves, contract pharmacies sell drugs purchased at 340B prices to patients who are ineligible to receive such 340B-priced drugs. *See infra* at ¶¶ 67-71.

63. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (2018) ("2018 GAO Report"), https://www.gao.gov/assets/gao-18-480.pdf. A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4, Berkeley Rsch. Grp. (Oct. 2020), https://tinyurl.com/3rk5v8nu. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached*

$29.9 billion in 2019; Now Over 8% of Drug Sales, Drug Channels (June 9, 2020), https://tinyurl.com/5n7bmw5m. In 2022, 340B purchases reached $53.7 billion, a $9.8 billion increase from 2021 and a nearly $50 billion increase from 2009. Fein 2023; *see also* Fein 2022 (purchases under 340B increased $5.9 billion between 2020 and 2021 alone).

64. Several federal watchdogs, including the U.S. Government Accountability Office ("GAO") and HHS's own Office of the Inspector General ("OIG"), have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful claims for 340B drugs. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."); *see also infra* at ¶ 70 (court opinions discussing these findings).

65. Here is how the system has evolved over recent years: Under the "replenishment model" now in widespread use by contract pharmacies, the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients)—at prices significantly above the 340B price. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ. Labor, & Pensions*, 115th Cong. 11 (2018) (statement of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) ("Maxwell Testimony"), https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)). Pharmacies sell those drugs at a price or a rate negotiated by the patient's insurer that is significantly higher than the 340B price.

And, on information and belief, covered entities *do not* retain title to the drugs throughout the process.

66. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify individuals with some relationship to a covered entity—purported covered entity "patients" who were not previously identified as covered entity "patients" at the time the drug was dispensed. *Novartis*, 2024 WL 2279829, at *3 (noting that the third-party administrators who run these algorithms "often receive a larger fee for every prescription deemed eligible for the discount").[2] These black-box algorithms likely result in contract pharmacies claiming prescriptions as 340B-eligible where the individual who was dispensed the drug is not a covered entity "patient." *See* HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.[3] This process operates in an "after-the-fact" manner inconsistent with the specific program guidance published by HRSA. Although that guidance provides that each prescription be verified as 340B eligible at the time of drug dispensing, no prescriptions are verified in this manner under the replenishment model. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996); *see Novartis*, 2024 WL 2279829, at *3 ("Only after dispensing the drugs

[2] *See, e.g.*, 2018 GAO Report at 2; Maxwell Test. at 11.

[3] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* Maxwell Test. at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B price because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), *see* Maxwell Test. at 11. This demonstrates how contract pharmacies can expand the definition of an eligible "patient" to cover additional, non-340B prescriptions. *See also Novartis*, 2024 WL 2279829, at *3 (remarking on this very issue).

do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount.").[4]

67. Under the replenishment model, after using some undisclosed process to identify drugs that may have been sold to purported patients of a covered entity, the pharmacies then purchase additional drugs at the 340B price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported patients. Again, this is done after the fact, without the benefit of data verifying that these newly identified 340B patient prescriptions were actually issued in connection with a patient visit to a covered entity.

68. Once those replenishment drugs are received, the cycle starts anew: the 340B-priced drugs are again commingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M. Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-00634-PGS-JBD (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

69. As is evident, the replenishment model simply seeks to lower the price of drugs for pharmacies and covered entities, not patients—by seeking to replenish contract pharmacy inventories with 340B-priced drugs. There is no dispute that the pharmacies could replenish their inventories by ordering the drugs at market prices, but they instead attempt to do so at 340B prices. There is also no dispute that 340B discounts are not required to be passed along to patients.

[4] This is one reason why claims for 340B-priced drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, at 5, PIONEER HEALTH (Mar. 2022), https://bit.ly/3MShVog.

70. This "replenishment" practice can provide a windfall for covered entities and pharmacies. *See* U.S. Gov't Accountability Off., GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 5 (2019), https://www.gao.gov/assets/gao-20-108.pdf (explaining that covered entities "purchase [340B-priced] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). As the D.C. Circuit noted, "[t]he covered entity, the pharmacy, and the third-party administrator [who runs the algorithms referenced above] often divvy up the spread between the discounted price and the higher reimbursement rate." *Novartis*, 2024 WL 2279829, at *3. Accordingly, "[e]ach of these actors . . . has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 2024 WL 2279829 at *3.

71. By contrast, patients routinely do not receive the benefit of the discount in the form of lower prescription costs. *See* Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, at 3, 12, IQVIA (2022), https://tinyurl.com/mvuy8276 (concluding that "most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts" and that stakeholders in the 340B program, such as contract pharmacies, are "profit[ing] from 340B revenue"); Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, at 6, IQVIA (2024), https://tinyurl.com/y9aeb727 ("If a substantial number of states pass [policies prohibiting the use of contract pharmacy restrictions], it could further accelerate 340B growth in the coming years" and "reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies.").

72. Both CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed, for example, that 340B profits are material to their finances. CVS Health Corp., Annual Report (SEC Form 10-K), at 22 (Feb. 8, 2023), https://bit.ly/3Sh3Dl1; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K), at 28 (Oct. 13, 2022), http://bit.ly/3kflVXh ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability."). And journalists have revealed how in many cases 340B price reductions are not passed on to vulnerable populations in the form of lower prices.[5]

73. Besides diverting 340B price reductions intended for vulnerable populations into the pockets of for-profit pharmacies, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

[5] *See also* Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL ST. J. (Dec. 20, 2022), https://tinyurl.com/bdhhzdhr (explaining that many hospitals do not pass on 340B discounts to their patients and that 340B appears to bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods); Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N. Y. TIMES (Sept. 24, 2022), https://tinyurl.com/28ubr4hd (explaining how one hospital "nakedly capitaliz[ed] on" 340B to turn a profit).

74. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A). Unlawful duplicate discounting forces the manufacturer to provide a discount on its drug twice-over—once under 340B to the covered entity, and again in the form of a rebate to the state Medicaid agency.

75. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (2020), https://www.gao.gov/assets/gao-20-212.pdf. As the GAO explains, this is because of the difficulty of auditing and obtaining reliable data for covered entities with "complex" networks of contract pharmacies. 2018 GAO Report at 45.

D. Covered Entities' Repeated Efforts To Expand 340B

76. Covered entities have repeatedly attempted to circumvent federal authority over 340B to impose their own preferred obligations on 340B manufacturers.

77. In 2006, covered entities filed suit against several pharmaceutical manufacturers, claiming that they had been overcharged for 340B-priced drugs in violation of the PPAs between manufacturers and the federal government. *Astra*, 563 U.S. at 116-17. In 2009, on review, the Supreme Court unanimously rejected such private actions as an alternative 340B enforcement mechanism, emphasizing the need for 340B to be uniformly administered with an eye toward implications for other federal healthcare programs. *Id.* at 120. As the Supreme Court held, "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. Rather than allowing "340B entities to launch lawsuits in district courts across the country," with the attendant "risk of conflicting adjudications," "Congress directed HRSA to create a formal dispute resolution procedure, institute

refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 120-21. "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework *the proper remedy*[.]" *Id.* at 121-22 (emphasis added).

78. Approximately ten years later, with the continued explosion in contract pharmacy arrangements, the increased use of the replenishment model and documented problems with program integrity, certain PhRMA members independently adopted new policies to address the 340B abuses reported by federal watchdogs. *See, e.g.*, First Am. Compl. at ¶¶48-52; *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF No. 13.

79. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS, Off. of the Sec'y, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020) ("Advisory Opinion"), https://tinyurl.com/2s4f924r (emphasis added); *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 55-56 (D. Del. 2021). Although the Advisory Opinion was subsequently vacated on other grounds, it confirms that even HHS concluded that, at a minimum, an agency relationship is required between a covered entity and its contract pharmacy, echoing prior HRSA guidance. 61 Fed. Reg. at 43,550, 43,555 (HRSA 1996 guidance stating that a covered entity without an in-house pharmacy could contract with *one* contract pharmacy to serve as its "agent").

80. In May 2021, HRSA issued letter decisions to the manufacturers that were implementing policies to address 340B abuses. *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are in Violation of the 340B Statute*, Health Res.

& Servs. Admin., HRSA Letter to AstraZeneca Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2nybf4z2 (last visited May 2024); HRSA Letter to Lilly USA, LLC Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/5xkem3y7 (last visited May 2024); HRSA Letter to Novartis Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/jytw6xd6 (last visited May 2024); HRSA Letter to Novo Nordisk Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/ycxwceaz (last visited May 2024); HRSA Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2veh5838 (last visited May 2024); HRSA Letter to United Therapeutics Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2p85wz8d (last visited May 2024). Litigation ensued.

81. In the context of those suits,[6] courts have repeatedly concluded that the scope of manufacturers' obligations does not encompass providing 340B-priced drugs to an unlimited number of contract pharmacies—the exact same requirement West Virginia seeks to impose here. Most recently, the D.C. Circuit rejected the assertion that 340B requires manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *Novartis*, 2024 WL 2279829, at *5. As the D.C. Circuit concluded, Congress chose to impose only certain restrictions on 340B-participating manufacturers—that they make a "bona fide" offer, i.e., that they "propose to sell covered drugs to covered entities at or below a specified monetary amount." *Id.* at *5. This means

[6] *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind.); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Becerra*, No. 1:21-cv-01479 (D.D.C.); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C.); *cf. Pharm. Rsch. & Mfrs. of Am. v. Becerra*, No. 21-cv-00198-PWG (D. Md.).

that manufacturers remain free to impose "conditions on the distribution of covered drugs to covered entities." *Id.* at *8.

82. And the D.C. Circuit similarly rejected the notion that purported silence allowed for imposition of an unlimited contract pharmacy requirement. As that court noted, purported "silen[ce] about delivery conditions . . . preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis*, 2024 WL 2279829 at *5. The court also noted that this silence did not mean that manufacturers have carte blanche as to conditions. *Id.* at *8. Instead, Congress carefully circumscribed the obligations it placed on manufacturers, only permitting conditions that would not move offers out of the realm of "bona fide" offers. *Id.* at *8. The court expressly left adjudication of "more onerous conditions" on offers than the ones before it and as-applied challenges to the manufacturer conditions to the federal government, reviewed by federal courts.

83. The Third Circuit's decision in *Sanofi* likewise rejected the very same obligation West Virginia seeks to impose here. 58 F.4th at 703-04. The Third Circuit noted that "Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* at 704 (340B does not "require[] delivery to an unlimited number of contract pharmacies"). The Third Circuit also expressly enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government "from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies"); *id.* at 704 (noting that "'Congress knew how to' grant covered entities permission to contract with third parties for distribution . . . but did

not" (quoting *State Farm Fire & Cas. Co. v. United States ex. Rel. Rigsby*, 580 U.S. 36, 39 (2016))).

84. In doing so, the Third Circuit concluded that, despite the statute's "silence" as to the number of permitted contract pharmacies, such an unlimited contract pharmacy requirement "overstepped the statute's bounds," as reflected in 340B's structure and other considerations. *Sanofi*, 58 F.4th at 707. The Third Circuit left open the possibility, however, that the federal obligation may require that manufacturers offer to deliver 340B-priced drugs to some pharmacies in certain circumstances (for example, a single contract pharmacy where a covered entity lacks its own in-house pharmacy). 42 U.S.C. § 256b(a)(1); *Sanofi*, 58 F.4th at 703-04. Thus, *Sanofi* ultimately recognizes there is no gap in 340B—instead the question requires interpretation of federal law. *Sanofi*, 58 F.4th at 705.

85. Two other courts are in accord. The U.S. District Court for the District of Columbia, in a subsequently affirmed decision, likewise found that the 340B statute permits drug manufacturers to impose reasonable conditions regarding contract pharmacies as part of the manufacturers' participation in 340B, including a reasonable limitation on where manufacturers will send 340B-priced drugs. *Novartis*, 2021 WL 5161783, at *7. In a similar vein, the U.S. District Court for the District of Delaware found that Congress chose not to require manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *AstraZeneca*, 543 F. Supp. 3d at 58-59.[7]

86. For their part, covered entities have sought to use the federal ADR mechanism, which is overseen by a panel within HHS, to enforce this purported obligation to provide 340B-priced drugs to any and all contract pharmacies identified by a covered entity. In those

[7] One appeal remains pending. *See Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

proceedings, a group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements." Those entities asked the panel "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." Petition for Damages and Equitable Relief ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2021/01/open-door-adr-petition.pdf?rev=99130335a69d448fafa0110cab3230f6&hash=676DEFD45F067461E1FB3E72CD3CA492; *see also* Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, *Univ. of Wash. Med. Ctr. v. AstraZeneca Pharms. LP* (HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

87. Dissatisfied with the outcomes in federal court and before the federal agency, covered entities turned their sights to lobbying states, seeking to impose on manufacturers, as a matter of state law, a pricing obligation in a federal program that federal courts have already concluded does not exist and cannot be imposed even by the federal agency tasked with 340B's administration and enforcement. While covered entities previously considered contract pharmacy use an issue of pricing, when moving to the states, they now portray such laws as imposing a mere "delivery" obligation on drug manufacturers. But SB 325 expressly imposes a pricing requirement on drug manufacturers.

88. The recently enacted Inflation Reduction Act ("IRA") also makes clear the interrelationship between 340B and Medicare, as well as highlighting once again the

quintessentially federal nature of the 340B pricing regime. The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS is to "negotiate" with manufacturers "maximum fair prices" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide drugs under these so-called maximum fair prices, except that they need not provide access to the maximum fair prices when drugs are 340B eligible and the 340B price is lower than the maximum fair price. *Id.* § 1320f-2(d). That is, manufacturers need not provide duplicate 340B and "maximum fair price" discounts. *Id.* To avoid duplicate discounting, this scheme necessarily requires identifying when a drug subject to the maximum fair price is dispensed as a 340B drug—further demonstrating the "interdependent nature" of Medicare and the 340B program. *Astra*, 563 U.S. at 120.

89. The Centers for Medicare and Medicaid Services ("CMS") has issued draft IRA guidance for avoiding duplicate discounting under the Medicare Drug Price Negotiation Program. Under that guidance, a manufacturer must "indicate[] that the claim for [a] selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the [maximum fair price] for the selected drug." CMS, Medicare Drug Price Negotiation Program, at 48.[8] To facilitate the identification of 340B drugs, the draft guidance encourages dispensing entities to use claims codes indicating drugs dispensed under the 340B program. *Id.* at 41. But West Virginia "consider[s] a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity . . . requiring a claim for a drug to include a modifier or be processed or resubmitted to indicate that the drug is a 340B drug." W. Va. Code § 33-51-9(d). Such prohibition—despite being ostensibly applicable to pharmacy benefit managers—will affect whether manufacturers use claim codes, and obscure the data manufacturers need to avoid duplicate discounts under the federal Medicare Drug

[8] Draft Guidance on the Medicare Drug Price Negotiation Program, https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (last visited May 18, 2024).

Price Negotiation Program. This conflict demonstrates yet another instance of the inherent tension between federal and state law as manufacturers attempt to identify "maximum fair prices" under the IRA's Medicare Drug Price Negotiation Program.

E. West Virginia Enacts SB 325 To Impose State-Law Conditions On 340B

1. SB 325's Passage And Requirements

90. On March 8, 2024, West Virginia enacted SB 325.

91. SB 325 expressly provides that its regulatory object is the federal 340B program. *See* W. Va. Code § 60A-8-6a(a)(1) ("'340B drug' means a drug that . . . is a covered outpatient drug within the meaning of 42 U.S.C. § 256b; . . . [h]as been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b(a)(1); and . . . [i]s purchased by a covered entity within the meaning of 42 U.S.C. 256b.").

92. SB 325 instructs that "[a] manufacturer . . . shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug, unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(1).

93. SB 325 defines "340B entity" to mean "an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. § 256b, including its pharmacy or pharmacies, or any pharmacy or pharmacies, contracted with the participating entity to dispense drugs purchased through such program." W. Va. Code § 60A-8-6a(2); *id.* § 33-51-3. Pharmacy is defined to include both pharmacies in-state *and* "any place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state." W. Va. Code § 60A-8-6a(2); *id.* § 30-5-4.

94. SB 325's text nowhere requires that drugs purchased at the 340B price that are provided to a pharmacy or "a location" be dispensed only to patients of a covered entity, as provided for by 340B. On the contrary, SB 325 expressly requires that a manufacturer cannot restrict or prohibit "a[ny] location authorized by a 340B entity" from purchasing or obtaining drugs at the 340B price in any circumstance. Because SB 325 defines 340B entity to include both 340B covered entities *and* contract pharmacies, SB 325 would bar a manufacturer from refusing to send 340B-priced drugs to *any* location that a contract pharmacy (not even a 340B covered entity) wants.

95. SB 325 also bars manufacturers "directly or indirectly" from requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to" a covered entity or contract pharmacy "unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(2). This provision is both preempted under federal law and directly restricts manufacturers' speech.

2. Enforcement

96. SB 325 does not acknowledge HRSA's enforcement authority or the congressionally mandated safeguards for administrative dispute resolution under 340B. It also does not consider the limitations on enforcement power Congress deemed necessary to maintain the 340B program's delicate balance.

97. Instead, SB 325 makes any violation of its provisions a violation of West Virginia's Unfair Trade Practices Act. W. Va. Code § 60A-8-6a(c)(1)(B). West Virginia's Unfair Trade Practices Act gives enforcement authority to the West Virginia Attorney General over violations of that provision.

98. The remedies and penalties provided for include a civil penalty of $50,000 per each violation, cease-and-desist orders, and restitution. W. Va. Code § 60A-8-6a(c)(A); *id.* § 46A-7-101; *id.* § 33-11-1.

99. These procedures and remedies differ dramatically from, and extend far beyond, the procedures and remedies that the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d). This includes West Virginia's provision of steep civil penalties.

100. SB 325 is to take effect on June 6, 2024.

101. SB 325 expressly rests its purported addition of a state law obligation on the existence of a preexisting federal obligation. W. Va. Code § 60A-8-6a(b)(1).

102. As a result, in any state enforcement proceeding, a state adjudicator will be required to answer multiple questions of federal law to determine if a manufacturer violated SB 325. These include, among other things, whether under *federal* law (1) a particular covered entity has permissibly contracted with a contract pharmacy under federal law and has the necessary "principal-agent" relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B); (2) the covered entity continues to "hold title" to the 340B-priced drugs throughout all relevant transactions (which does not occur under the prevailing "replenishment model"); (3) all of the individuals receiving 340B-priced drugs meet the federal definition of a 340B patient; (4) the particular prescriptions at issue qualify for 340B prices; and (5) the 340B price reductions are duplicative of Medicaid rebates applicable to the same prescriptions, *id.*§ 256b(a)(5)(A). For example, a covered entity that sells or transfers 340B-priced drugs to anyone other than its patients is no longer eligible to receive 340B-priced drugs. *Id.* § 256b(a)(5). Similarly, covered entities violating prohibitions on duplicate discounts are ineligible to receive any 340B-priced drugs. *Id.* § 256b(a)(4)-(5). Under SB 325, a West Virginia state adjudicator

court will be required to make these determinations to adjudicate any purported violation of SB 325.

3. Ban On Speech

103. In addition to those intrusions and conflicts, SB 325 directly regulates and bars certain speech based on its content. SB 325 bars manufacturers "directly or indirectly" from requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to" a covered entity or contract pharmacy "unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(2).

104. That restriction directly bans manufacturers from engaging in certain speech and restricts their access to information.

CLAIMS FOR RELIEF

CLAIM I
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute)

105. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

106. Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

107. SB 325's forced sale, speech-restriction, and state-law enforcement provisions are preempted because they intrude upon the exclusive field created by 340B and, worse, do so in a way that directly conflicts with the federal statute's terms and in a manner that is likely to generate conflict between state and federal regulators.

108. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is

a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

109. Field preemption is especially likely where a state law "'diminish[es] the [Federal Government]'s control over enforcement' and 'detract[s] from the integrated scheme of regulation' created by Congress." *Id.* at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

110. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 120 (noting the "interdependent" nature of 340B with other federal programs). No room exists for state supplantation in this field. Congress created the exclusively federal field here through enactment of 340B. *See supra* at ¶¶ 39-59. Unlike some other federal healthcare programs, where Congress has assigned the states significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); 42 U.S.C. § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

111. The system crafted by Congress did not impose open-ended obligations on manufacturers. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed and limited system. Congress carefully defined those eligible to receive 340B drugs (enumerated covered entities), set the nature of the benefit (a set ceiling price calculation), and imposed limitations on that benefit (to whom covered entities may furnish 340B-priced drugs). Congress spoke in exacting detail because 340B, given its interconnection with other federal programs, must maintain a delicate balance to ensure that the program achieves its

purpose without becoming too onerous for manufacturers, reinforcing that this is an area of dominant federal concern. Finally, Congress set out an exclusive federal enforcement scheme to maintain the program as a harmonious whole.

112. SB 325 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding the scope of manufacturers' obligations to include providing 340B-priced drugs to an unlimited number of contract pharmacies, and by implementing its own competing enforcement regime. *See* W. Va. Code § 60A-8-6a(a)(1) (defining 340B drug as "a covered outpatient drug within the meaning of 42 U.S.C. § 256b; . . . [h]as been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b(a)(1); and . . . [i]s purchased by a covered entity within the meaning of 42 U.S.C. 256b."). That is far more than 340B requires, permits, or contemplates. *Sanofi*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating what West Virginia is now attempting to do).

113. That intrusion into the field of the operation of 340B is made clear by SB 325's scope. West Virginia pharmacies can freely order any drug legally available to them at market pricing. SB 325 does not seek to expand access to drugs generally—it merely seeks to compel 340B pricing for drug orders. 340B's reticulated scheme regarding who can receive 340B-priced drugs thus directly occupies the arena into which West Virginia has stepped. SB 325's imposition of additional obligations and a separate enforcement scheme is accordingly preempted.

114. SB 325 is also conflict preempted. Conflict preemption arises when "it is impossible to comply with both state and federal law" or when "'the state law stands as an obstacle to the accomplishment of the full purposes and objectives' of federal law." *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 191-192 (4th Cir. 2007) (quoting *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301,

1305 (4th Cir. 1992)). A conflict exists between the 340B statute and federal PPAs, on the one hand, and SB 325's forced sale and data provisions, on the other, for several reasons.

115. *First*, 340B requires only that manufacturers "offer" 340B-priced drugs to covered entities (*i.e.*, that they provide some meaningful path for covered entities to access these medications). *See* 42 U.S.C. § 256b(a)(1); *Novartis*, 2024 WL 2279829 at *5-6; *Sanofi*, 58 F.4th at 703. Congress placed strict limits on the types of entities entitled to 340B pricing (contract pharmacies are not included) and the scope of the required offer by manufacturers. Congress also expressly prohibited any covered entity from reselling or otherwise transferring a drug bought at the 340B price to anyone other than its patients. 42 U.S.C. § 256b(a)(5)(B). Several PhRMA members have already noted in pending litigation that because a retail pharmacy is not a "patient of [a covered] entity," it is prohibited by federal statute from receiving 340B-priced drugs. *See, e.g.*, Pls.' Combined Mem. In Supp. Of Pls.' Cross-Mot. For Summ. J. & In Opp'n To Defs.' Mot. To Dismiss Or, In The Alternative, For Summ. J. at 29, *Eli Lilly & Co. v. Azar*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 10, 2021), ECF No. 89.

116. By mandating that manufacturers provide those 340B-priced drugs to any and all contract pharmacies that a covered entity chooses to contract with, the West Virginia statute dramatically expands manufacturers' obligations under the federal program. And it seemingly requires manufacturers to do so even where covered entities do not, as required by federal law, retain title to the drugs or have the requisite principal-agent relationship with contract pharmacies. Indeed, West Virginia is now seeking to impose as a matter of state law what even the federal government has been enjoined from requiring of manufacturers under federal law, in connection with an exclusively federal program. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 2024 WL 2279829, at *8. As courts have recognized, this expansion of obligations under a federal incentive

program are preempted. *Forest Park II v. Hadley*, 336 F.3d 724, 732-33 (8th Cir. 2003) (holding states may not impose additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations). West Virginia's efforts conflict with both the plain text of 340B's requirements, and Congress's desire to create a carefully circumscribed and federally managed closed system.

117. Nor can SB 325 be saved by recasting it as a distribution requirement. West Virginia is attempting to regulate who can receive 340B-priced drugs, not drugs in general. No one suggests that manufacturers will not provide market-priced drugs to pharmacies. The aim instead is to force manufacturers to provide those same drugs to those same pharmacies at a lower price. Indeed, absent the pricing requirement, West Virginia's law would be meaningless. *See* W. Va. Code § 60A-8-6a(a)(1) (defining "340B drug" in reference to the federal statutory price).

118. *Second*, the West Virginia statute's broad prohibition on manufacturers "directly or indirectly" requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to," it "unless the claims or utilization data sharing is required by the United States Department of Health and Human Services" is preempted. W. Va. Code § 60A-8-6a(b)(2). In order to utilize the federal administrative dispute resolution mechanism, manufacturers must first audit a covered entity. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). However, manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates there is reasonable cause." 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibition on transfer or sale, or the prohibition on duplicate discounting. *Id.* Accordingly, to even access the audit process to engage in an ADR proceeding, manufacturers must be able to access information

that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions. West Virginia's bar on requesting "any claims or utilization data" handicaps manufacturers from being able to meaningfully utilize the federal resolution process that Congress provided.

119. *Third*, SB 325's state-law enforcement provision both conflicts with the carefully calibrated system created by Congress to ensure 340B compliance and raises the specter of inconsistent adjudications. W. Va. Code § 60A-8-6a(c). Among other reasons, SB 325 conflicts because it skews the carefully balanced enforcement scheme enacted by Congress. Congress specified that a manufacturer may be held liable only when it "*knowingly and intentionally*" overcharges a covered entity. 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (setting a maximum of $5,000 per violation); *see also* 88 Fed. Reg. 69,531, 69,535 (Oct. 6, 2023) (making inflation adjustment to $6,813). SB 325, however, destroys that calibrated system by specifying a penalty of *$50,000 per violation*, which is defined in terms of the smallest saleable unit of the drug. That type of draconian penalty wildly unbalances Congress's system, and raises the specter of inconsistent adjudications identified in *Astra* because West Virginia cannot enforce SB 325 without adjudicating multiple questions of federal law, such as determining whether an entity is "authorized to participate in 340B drug pricing"—an issue determined exclusively under the federal 340B statute. *See* W. Va. Code § 60A-8-6a(a)(2) (defining 340B entity by reference to the federal definition); 42 U.S.C. § 256b(a)(4).

120. *Fourth*, SB 325 frustrates the "accomplishment of the full purposes and objectives of [Congress,]" *Anderson*, 508 F.3d at 192 (quoting *Worm*, 970 F.2d at 1305), in various ways in addition to those described above. For example, by purporting to impose additional, onerous terms on 340B (including terms the Third Circuit has held not even the federal government can impose),

SB 325 increases the cost of participation in the federal Medicare Part B and Medicaid programs. As another example, SB 325's mandates will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients, both of which the federal scheme forbids. In addition, SB 325 conflicts with the federal Medicare Drug Price Negotiation Program by frustrating the disclosure of claims data that is necessary to prevent duplicate discounting with the "maximum fair prices" established under the Inflation Reduction Act. *See* 42 U.S.C. § 1396r-8(a)(5)(C).

121. For all of these reasons, SB 325's forced sale, data policy, and state-law enforcement provisions are preempted, and their enforcement should be enjoined. *Cox v. Shalala*, 112 F.3d 151, 154 (4th Cir. 1997) (Preemption may be implied where federal law "regulat[es] so pervasively that there is no room left for the states to supplement federal law" or when "compliance with both federal and state regulations is a physical impossibility." (internal quotation marks and citation omitted)); *Columbia Venture, LLC v. Dewberry & Davis, LLC*, 604 F.3d 824 (4th Cir. 2010).

CLAIM II
(Declaratory/Injunctive Relief—Violation of the First Amendment to the United States Constitution)

122. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

123. The Free Speech Clause of the First Amendment of the United States Constitution provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Fourteenth Amendment of the United States Constitution makes the Free Speech Clause applicable to the states. U.S. Const. amend. XIV, § 1.

124. SB 325 bars manufacturers "directly or indirectly" from requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to" a covered entity or contract pharmacy

"unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." W. Va. Code § 60A-8-6a(b)(2). In other words, SB 325 prohibits manufacturers from receiving certain information from covered entities or contract pharmacies. The law thus restricts speech in addition to "gather[ing] information," which is constitutionally protected "as a predicate to speech." *People for the Ethical Treatment of Animals, Inc. v. N.C. Farm Bureau Fed'n, Inc.*, 60 F.4th 815, 829 (4th Cir. 2023), *cert. denied sub nom.*,144 S. Ct. 325 (2023).

125. SB 325 is a content- and speaker-based restriction on speech. A content-based restriction limits speech "because of the topic discussed or the idea or message expressed." *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015); *see id.* ("Some facial distinctions based on a message are obvious, defining regulated speech by particular subject matter."). A restriction is speaker-based if it "disfavors specific speakers." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 564 (2011). SB 325 is content-based because it applies to requests for "claims or utilization data," and it is speaker-based because it applies specifically to manufacturers and manufacturers' agents and affiliates. W. Va. Code § 60A-8-6a(b)(2).

126. Both content- and speaker-based restrictions are subject to strict judicial scrutiny. *Reed*, 576 U.S. at 164-65 (content-based restriction is subject to strict scrutiny); *Sorrell*, 564 U.S. at 564 (same for speaker-based restriction). Strict scrutiny requires the state to show both that (1) "the restriction furthers a compelling interest" and (2) "is narrowly tailored to achieve that interest." *Reed*, 576 U.S. at 171 (citation omitted).

127. SB 325 fails both prongs of strict scrutiny review. West Virginia cannot "prove that the restriction furthers a compelling interest," nor can it prove that the restriction "is narrowly tailored to achieve that interest." *Id.*

128. SB 325 fails even if it is assessed under intermediate scrutiny. West Virginia cannot show "that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Sorrell*, 564 U.S. at 572.

129. For these reasons, SB 325 is invalid under the First Amendment and the Due Process Clause of the Fourteenth Amendment.

CLAIM III
(Declaratory/Injunctive Relief—Unconstitutional Extraterritorial Regulation)

130. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

131. Under our constitutional framework, states may not directly regulate conduct that takes place wholly in another state. "[A]ll States enjoy equal sovereignty." *Shelby Cnty. v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted).

132. While the Supreme Court recently clarified that state laws regulating conduct within the state's borders in a way that might have an "extraterritorial effect" in other states are not categorically barred, it also made clear that it was not addressing a state law that "directly regulated out-of-state transactions." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374, 376 n.1 (2023). Accordingly, it remains true that a state may not regulate conduct that occurs in another state and that is not directed within its borders.

133. The understanding that states may not impose on other states' regulatory powers follows from several Constitutional provisions. States are denied certain powers that a sovereign

might ordinarily impose, U.S. Const. art. I, § 10; and required to honor certain rights of other states, U.S. Const. art. IV, §§ 1, 2, 3. Similarly, the Due Process Clause limits a state's ability to regulate conduct occurring wholly outside its borders. *See Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954) (recognizing "the due process principle that a state is without power to exercise 'extra territorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries"); *Home Ins. Co. v. Dick*, 281 U.S. 397, 407-08 (1930) (similar).

134. The Commerce Clause provides that "[t]he Congress shall have Power … To regulate Commerce … among the several States." U.S. Const. art. I, § 8, cl. 3. Under that clause, states are prohibited from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335-36 (1989); *see also, e.g.*, *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.). While the Court recently refined the reach of the dormant Commerce Clause, it did not disturb its prior precedent establishing that state laws are unconstitutional where they "directly regulate[] out-of-state transactions by those with no connection to the State." *Ross*, 598 U.S. at 374, 376 n.1.

135. SB 325 is unconstitutional under these principles. SB 325 broadly bans all pharmaceutical manufacturers, many of whom have no physical presence in West Virginia, from "either directly or indirectly, deny[ing], restrict[ing], or prohibit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug." W. Va. Code § 60A-8-6a(b)(1). In turn, SB 325 defines 340B entity to mean any covered entity under federal law or any pharmacy contracted with a covered entity. W. Va. Code § 60A-8-6a(2); *id.* § 33-51-3. The *sole* geographic limitation is contained in the definition of pharmacy, which covers in-state pharmacies but *also* applies to any out-of-state pharmacy "where drugs are

dispensed and pharmacist care is provided to residents of this state." W. Va. Code § 60A-8-6a(a)(8); *id.* § 30-5-4. In other words, the statute purports to regulate any out-of-state pharmacy so long as that pharmacy has shipped a drug to a resident of West Virginia at some point.

136. Much of the conduct regulated by SB 325's forced sale provision will occur wholly beyond the borders of West Virginia. For example, SB 325 will apply to out-of-state transactions between out-of-state manufacturers and out-of-state distributors. It will also apply to out-of-state transactions between out-of-state manufacturers or out-of-state distributors, on one side, and out-of-state covered entities on the other. The only qualifier limiting SB 325's reach is that an out-of-state pharmacy must have shipped drugs to a West Virginia resident at some point. Therefore, SB 325 will operate even where the transactions occur out-of-state and involve only out-of-state actors.

137. SB 325 also bars manufacturers "directly or indirectly" from requiring a covered entity or a contract pharmacy "to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to" a covered entity or contract pharmacy. W. Va. Code § 60A-8-6a(b)(2). Again, this provision will primarily regulate out-of-state conduct. The statutory provision places no geographic limitation on its application to covered entities. As a result, it governs out-of-state manufacturers' transactions that occur outside of West Virginia with out-of-state covered entities. The same is true as to transactions between out-of-state manufacturers and out-of-state pharmacies, given that SB 325 sweeps in any out-of-state pharmacy, so long as it has dispensed drugs to a West Virginia resident in the past. And paradoxically, of course, West Virginia's unconstitutional bar on requiring claims or utilization data means that manufacturers are barred from requesting information that might somehow allow them to narrow the reach of West Virginia's law.

138. Finally, the extraterritorial reach of the SB 325 is further heightened by the remedies available for violations of SB 325. The West Virginia Attorney General is empowered under SB 325 to issue cease-and-desist orders, among other things. W. Va. § 60A-8-6a(c)(A); *id.* § 46A-7-101; *id.* § 33-11-1. Of course, given that much of the conduct regulated will occur out of state, SB 325 gives its Attorney General authority to regulate conduct far outside of its borders—conduct that is likely entirely lawful in the state in which it actually occurs.

139. By directly regulating commerce that occurs entirely outside of its borders, SB 325 violates the Constitution's bar on extraterritorial state regulation. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666-71 (4th Cir. 2018) (striking down a Maryland drug-pricing law that "directly regulates the price of transactions that occur outside Maryland[,]" where the law allowed "Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland").

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that SB 325 is unconstitutional and violates federal law;

b. issue an order and judgment declaring that SB 325 does not require PhRMA's members to offer 340B pricing on their covered outpatient drugs to contract pharmacies in West Virginia or contract pharmacies located outside of West Virginia that fall within the ambit of the statute;

c. enjoin, preliminarily and permanently, the implementation and enforcement of SB 325 against PhRMA's members;

d. enjoin, preliminarily and permanently, the implementation and enforcement of SB 325 as to the sale of PhRMA's members' drugs under 340B;

e. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

f. grant any other relief the Court finds just and appropriate.

Dated: May 31, 2024

Respectfully submitted,

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